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ATTORNEY DOCKET NO. CONFIRMATION NO. FIRST NAMED INVENTOR APPLICATION NO. FILING DATE 7475 Takashi Horiuchi 084335/0135 07/09/2001 09/807,409 **EXAMINER** 02/25/2004 LAMBERTSON, DAVID A Stephen B Maebius Foley & Lardner ART UNIT PAPER NUMBER 3000 K Street N W Suite 500 Washington, DC 20007-5109 1636

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/807,409	HORIUCHI ET AL.
	Examiner	Art Unit
	David A. Lambertson	1636
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1) Responsive to communication(s) filed on 12 September 2001.		
2a) ☐ This action is <b>FINAL</b> . 2b) ☐ This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4)⊠ Claim(s) <u>1-20</u> is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)☐ Claim(s) is/are rejected.		
7) Claim(s) is/are objected to.		
8)⊠ Claim(s) <u>1-20</u>		
are subject to restriction and/or election requirement.		
Application Papers		
9) The specification is objected to by the Examiner.		
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
12)□ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)□ All b)□ Some * c)□ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage		
application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
Attachment(s)		
1) Notice of References Cited (PTO-892)	4) Interview Summary	
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail D 5) Notice of Informal I 6) Other:	Pate Patent Application (PTO-152)

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## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6 and 19, drawn to a method for amplifying a gene using a protein that blocks replication fork progression.

Group II, claim(s) 7, drawn to a polypeptide comprising SEQ ID NO: 25.

Group III, claim(s) 7, drawn to a polypeptide comprising SEQ ID NO: 26.

Group IV, claims 8-11, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 25, or that hybridizes to SEQ ID NO: 27, and vectors comprising said polynucleotide.

Group V, claim(s) 8-11, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 26, or that hybridizes to SEQ ID NO: 28, vectors comprising said polynucleotide.

Group VI, claim(s) 12-18 and 20, drawn to expression vectors comprising a foreign gene in proximity to a recombination hot spot and an autonomously replicating sequence, host cells comprising said vector, and methods of producing a protein of interest using said host cells.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is the ability to amplify a gene of interest using any protein that has the capacity to block replication fork progression.

The special technical feature of Group II is the particular amino acid sequence set forth as SEQ ID NO: 25. This special technical feature is different from the special technical feature of Group I because Group I does not require the presence of any particular protein sequence, let alone the specific sequence of SEQ ID NO: 25. Because no particular sequence is required to practice the

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claimed method, the special technical feature of SEQ ID NO: 25 cannot be commensurate with the special technical feature of Group I, which does not relate to the specific sequence.

The special technical feature of Group III is the particular amino acid sequence set forth as SEQ ID NO: 26. This special technical feature is different from the special technical feature of Group I because Group I does not require the presence of any particular protein sequence, let alone the specific sequence of SEQ ID NO: 26. Because no particular sequence is required to practice the claimed method, the special technical feature of SEQ ID NO: 26 cannot be commensurate with the special technical feature of Group I, which does not relate to the specific sequence.

The special technical feature of Group IV is the specific nucleotide sequence that encodes SEQ ID NO: 25 or that hybridizes to SEQ ID NO: 27. This special technical feature is different from the special technical feature of Group I because Group I does not require the presence of any particular nucleotide sequence encoding any particular protein sequence, let alone the specific nucleotide sequence encoding the particular protein sequence of SEQ ID NO: 25. Because no particular sequence is required to practice the claimed method, the special technical feature of Group IV cannot be commensurate with the special technical feature of Group I, which does not relate to the specific sequence.

The special technical feature of Group V is the specific nucleotide sequence that encodes SEQ ID NO: 26 or that hybridizes to SEQ ID NO: 28. This special technical feature is different from the special technical feature of Group I because Group I does not require the presence of any particular nucleotide sequence encoding any particular protein sequence, let alone the specific nucleotide sequence encoding the particular protein sequence of SEQ ID NO: 26. Because no particular sequence is required to practice the claimed method, the special technical feature of Group IV cannot be commensurate with the special technical feature of Group I, which does not relate to the specific sequence.

The special technical feature of Group VI is a vector, host cell containing the vector and method of using the host cell to produce a protein of interest. This special technical feature is different from the special technical feature because the method is directed to the production of a protein, and this is a different compound than the gene that is amplified in the method of Group I. Because the methods are directed to the production of different products, the special technical features are different.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D. AU 1636

JAMES KETTER PRIMARY EXAMINER